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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,932	02/20/2004	Michael N. Helmus	BSCI-006/00US	9710

22903 7590 10/02/2008
COOLEY GODWARD KRONISH LLP
ATTN: PATENT GROUP
Suite 1100
777 - 6th Street, NW
WASHINGTON, DC 20001

EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

MAIL DATE	DELIVERY MODE
10/02/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/781,932	HELMUS ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI, Ph.D.	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 8-38* is/are pending in the application.

4a) Of the above claim(s) *3,8-18,20-24 and 33* is/are withdrawn from consideration.

5)☒ Claim(s) *38* is/are allowed.

6)☒ Claim(s) *1, 2, 4, 5, 19, 25, 27-32, and 34-37* is/are rejected.

7)☒ Claim(s) *26* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to the amendment filed on June 19, 2008.

2. Claims 6 and 7 have been cancelled previously.

3. New claim 38 has been added.

4. Claims 3, 8-18, 20-24, and 33 have been withdrawn previously.

5. Claims 1, 2, 4, 5, 19, 25-32, 34-37, and 38 are currently under examination.

Withdrawal of Rejections

6. The rejection of claims 1, 4, 5, 25, 27-32, and 34-37 under 35 U.S.C. 102(b) as being anticipatd by Samuel et al. (Human Gene Therapy 13: 791-802 (2002)) is withdrawn based on the amendment to the claims to remove the RGD peptide.

7. The rejection of claims 1, 2, 4, 5, 19, 28, 31, and 35 under 35 U.S.C. 102(e) as being anticipated by Burg (U.S. Patent 6,991,652 B2) is withdrawn based on the amendment to the claims to remove the RGD peptide.

8. The rejection of claims 1, 2, 4-6, 19, 25, 26, and 31 under 35 U.S.C. 102(e) as being anticipated by Miyamoto (U.S. 2004/0136977 A1; previously cited) is withdrawn based on the amendment to the claims to remove the RGD peptide.

Pending Rejections

Claim Rejections - 35 USC § 112

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. In claim 19, it is unclear how a "hydrogel" describes a synthetic polymer.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1, 4, 5, 25, 27-32, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (JP 06128289).

Mori et al. disclose the preparation of cell-adhesive peptide bonded to polysaccharides. Polysaccharides bonded to peptides X-Tyr-Ile-Gly-Ser-Arg-Y (X = absent, Glu, Asp; Y = NR1R2; R1, R2 = H, C1-4 alkyl) are prepared, which contain cell-adhesive core sequence of cell adhesive protein laminin. Typical polysaccharides are chondroitin sulfate, hyaluronic acid, and (carboxymethyl)chitin. These peptide-polysaccharide conjugates retain various biological activities of laminin, show high serum stability, more potent cell adhesiveness than the core sequence of laminin, and little side-effects, and are useful as cancer metastasis inhibitors. Thus, H-Tyr-Ile-Gly-Ser-Arg-NHCHMe2.2AcOH (I) was prepared by the solution method and

condensed with carboxymethyl chitin by using 1-ethyl-3-(3-dimethylaminopropyl)carbodiimide in 200 mM phosphate buffer (pH 7.4) to give (I)-carboxymethyl chitin conjugate containing 23 wt.% peptide. In cancer metastasis assay, the latter glycopeptide reduced number of colonies of B16-BL6 melanoma cells formed in lungs of mice from 177±28 (control group) to 17±9. (see Abstract).

The claims are reasonably interpreted such that the bioactive polymer can be the same biocompatible polymer, because withdrawn claim 3 is drawn to an embodiment where the polymers are explicitly recited as different. Therefore, Mori et al. disclose cross-linking Tyr-Ile-Gly-Ser-Arg with chondroitin sulfate, wherein the Tyr-Ile-Gly-Ser-Arg-chondroitin sulfate is the bioactive polymer comprising a Tyr-Ile-Gly-Ser-Arg peptide and a proteoglycan subunit (chondroitin-sulfate). The polymer is a miscible blend of peptide and chondroitin-sulfate. Applicant's disclosure of figure 1 describes a graft as a covalent linkage between the biocompatible polymer and the bioactive polymer, therefore the covalent cross-linking of the Tyr-Ile-Gly-Ser-Arg-chondroitin sulfate is reasonably interpreted as encompassing a graft polymer.

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). Therefore, the prima facie case can be rebutted by evidence showing that the

prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

14. Claims 1, 4, 5, 25, 27-32, and 34-37 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamora (U.S. Patent 7,297,343 B2).

Zamora discloses a wound dressing comprising a polymeric film having complexed thereto by hydrophobic interaction a construct comprising a polyanion covalently bonded to a hydrophobic prosthetic moiety, with a first bioactive molecule directly complexed to the polyanion wherein the polyanion is a construct of Formula I as recited in claim 1 via a covalent bond, thereby forming a silyl-heparin covalent complex, with a first bioactive molecule directly complexed to the heparin-activity molecule, wherein the silyl-heparin covalent complex comprises [benzyl-bis(dimethylsilylmethyl)]-(N-heparinyl)-carbamate or [benzyl-tris(dimethylsilylmethyl)]-(N-heparinyl)-carbamate, wherein the heparin-activity molecule is heparin, heparan sulfate, hyaluronic acid, dextran, dextran sulfate, chondroitin sulfate, dermatan sulfate, a molecule including a mixture of variably sulfated polysaccharide chains composed of repeating units of D-glucosamine and either L-iduronic or D-glucuronic acids, salts of any of the foregoing, derivatives of any of the foregoing, or combinations of any of the foregoing. The bioactive molecule is disclosed to encompass laminin (col. 3, lines 9-11).

Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for

believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir.1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.

Claim Objections

15. Claim 26 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 38. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). The claims encompass overlapping subject matter when the peptide is a dRGD, YIGSR, or an IVKAV peptide.

16. Claim 26 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Claims 1, 4, 5, 25, 27-32, and 34-37 are rejected.

18. Claim 26 is objected.

19. Claim 38 is allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI, Ph.D. whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

September 27, 2008
/ANAND U DESAI, Ph.D./
Examiner, Art Unit 1656